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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,589	03/29/2004	Eric Tomasetti	TR-6132 (BXTC 4021)	2100
Mr. Joseph B. E	7590 10/28/200 Barrett	EXAMINER		
Baxter Healthca	are Corporation	MCCLELLAND, KIMBERLY KEIL		
One Baxter Parkway, DF3-2W Deerfield, IL 60015			ART UNIT	PAPER NUMBER
			1791	
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			10/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/811,589	TOMASETTI ET AL.			
		Examiner	Art Unit			
		KIMBERLY K. MCCLELLAND	1791			
Period fo	The MAILING DATE of this communication a or Reply	ppears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)🖂	Responsive to communication(s) filed on 23	<i>July 2009</i> .				
2a)⊠	This action is FINAL . 2b) ☐ The	nis action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
 4) Claim(s) 1,2,5-16,18-22, 24-25, and 27 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 18-22,24 and 27 is/are allowed. 6) Claim(s) 1,2,5-16 and 25 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Applicati	on Papers					
9)□	The specification is objected to by the Exami	ner.				
10)🛛	10)⊠ The drawing(s) filed on <u>29 <i>March</i> 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.					
	Applicant may not request that any objection to the	ne drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4)				
Information Disclosure Statement(s) (PTO/SB/08) Solution Sol						

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DETAILED ACTION

Drawings

Do to the current amendment, the objection to the drawings is withdrawn.

Claim Rejections - 35 USC § 112

1. Do to the current amendment, the rejections under 35 U.S.C. 112, first paragraph are withdrawn.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-2, 5-9, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer.
- 4. With respect to claim 1, Yang et al. discloses a method for connecting flexible tubing wherein the tubing is placed in an axial end-to-end position (See Figures 2A and 2B), using a laser directed to heat the tube ends (paragraph 0068), positioning a sheet of material (i.e. drum head) between the axial surfaces of the tubing sections (See paragraph 0072), moving the two tubing sections to bring the axially facing surfaces of the two tubing sections into engagement with the sheet, and directing the

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electromagnetic beam generally toward the tubing ends for welding the two sections of tubing together (paragraph 0071). Yang also discloses the sheet material is formed from a separate sheet of material (610) attached to the axial surface at the end of a tubing section, the sheet being formed of a material which absorbs energy of an electromagnetic beam; directing the electromagnetic beam onto the sheet for welding tubing sections together (See paragraphs 0072 and 0131-0139). However, Yang et al. does not specifically disclose maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding environment until and during welding.

- 5. Spencer discloses an apparatus for welding together two sections of tubing, including a method of welding two tubing sections together and maintaining interior passages of the two tubing sections so as to be free from exposure to the surrounding environment until and during welding (See Figures 5-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the tubing sections free from exposure to the environment until and during welding as taught by Spencer in the method of Yang et al. The motivation would have been to prevent contamination in the tubing or patient (column 5, lines 25-27).
- 6. As to claim 2, Yang et al. is silent as to the temperature of the tubing ends before the laser is activated. However, in order for the tubing to be in a solid state prior to the welding process, the temperature of the tubing ends must be below the melting temperature of the material forming the tubing section. Yang et al. discloses that the laser melts the tubing (paragraph 0069).

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7. As to claim 5, Yang et al. discloses that the tubing material is substantially transparent (not laser responsive) to the electromagnetic beam (paragraph 0127).

- 8. As to claim 6, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071) and flow outward when heated (paragraph 0072).
- 9. As to claim 7, Yang et al discloses that dye may be applied to the tube ends (areas to be joined) that are welded by the laser (paragraph 0129).
- 10. As to claim 8, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071).
- 11. As to claim 9, Yang et al. discloses a method for connecting two pieces of tubing as disclosed above. Yang et al. also discloses that all the welding method is carried out in the axial position (See Figures 4A-4F). However, Yang does not disclose cutting off end portions of the tubing sections.

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12. Spencer discloses an apparatus for welding together two sections of tubing, including a method of cutting of end sections of tubing prior to welding (column 3, lines 14-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of cutting the tubing sections prior to welding, as taught by Spencer, with the laser welding method of Yang et al. in the axial position in order to ensure proper connection during welding.

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- 13. As to claim 16, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071), and flow outward (paragraph 0072).
- 14. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer as applied to claims 1-2, 5-9, and 16 above, and further in view of U.S. Patent No 4,832,773 to Shaposka et al.
- 15. Yang et al., Spencer, and Savitski disclose a method of welding tubing sections together. Spencer also teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40). However, Yang et al., Spencer, and Savitski et al. do not disclose the clamping of the tubing.
- 16. As to claim 10, Shaposka et al. discloses a method for connecting sections of tubing, including clamping the cut (pre-cut) tubing sections (column 3, lines 48-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of clamping the tubing sections, as taught by Shaposka et

al., with the laser welding method of Yang et al. and Spencer to keep the tubing sections stationary.

- 17. As to claim 11, Yang et al. discloses sealing the tube ends prior to welding the tubing sections together (paragraph 0072).
- 18. As to claim 12, Yang et al. discloses the use of a weld block (drum head) to absorb energy from the laser and combine with the tube (paragraph 0072).
- 19. As to claim 13, Spencer teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40).
- 20. As to claim 14, Spencer teaches the movement of welded tubing (weld sample) from one location (device) to a remote location (vise column 3, line 62- column 4, line 12).
- 21. As to claim 15, Yang et al. discloses that all the welding method is carried out in the axial position (See Figures 4A-4F).
- 22. As to claim 23, Yang et al. discloses the step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces of the of the tubing sections (See Yang et al. paragraph 0066), wherein the sheets are capable absorbing the energy of the electromagnetic beam (See Yang et al. paragraph 0072).
- 23. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer as applied to claims 1-2, 5-9, and 16 above, and further in view of U.S. Patent No 4,948,062 to Mahar et al.

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24. With respect to claim 25, Yang et al. does not specifically disclose extending the sheet of material between a supply roll and a take-up roll.

25. Mahar et al. discloses a method of dispensing film, including extending a sheet of material between a supply roll and a take-up roll (see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the supply and take-off roll dispensing method taught by Mahar et al. with the sheet material of Yang et al. The motivation would have been to dispense the sheet material without twisting or the formation of knots.

Allowable Subject Matter

- 26. Claims 18-22, 24, and 27 are allowed.
- 27. The following is a statement of reasons for the indication of allowable subject matter:
- 28. The prior art of record neither discloses nor suggests the steps of sealing a clamped tubing section with an absorption member in a collapsed configuration through electromagnetic radiation, removing the absorption member, and welding two tubing sections together through a separate intermediate sheet placed on the axially facing surfaces of the tubing sections with electromagnetic radiation. The closest prior art of record, U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. discloses many features of the claimed connecting method, but does not disclose or fairly suggest the step of removing the absorption member, nor is there any obvious

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reason to do so. Consequently, claims 18-22, 24, and 27-28 are found to distinguish over the prior art.

Response to Arguments

- 29. Applicant's arguments filed 07/23/09 have been fully considered but they are not persuasive.
- 30. With respect to applicant's arguments that Yang does not disclose brining the axially facing tubing section into contact with the drum head, examiner disagrees. Yang discloses the tubing sections are provided separately from drum heads (paragraph 0132). It is inherent the tubing section must be moved into contact with the drum head in order for the drum head to be attached onto the axial face of the tubing section. It is improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order. Altiris Inc. v. Symantec Corp., 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003). Therefore, the method taught by Yang reads on the currently claimed invention.
- 31. Applicant's remaining arguments are drawn to the dependency claims 2, 5-16, and 25-26 on independent claim 1. These arguments are not persuasive for the reasons noted above.

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Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KIMBERLY K. MCCLELLAND whose telephone number is (571)272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Thr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip C. Tucker can be reached on (571)272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. K. M./ Examiner, Art Unit 1791

KKM

/Philip C Tucker/ Supervisory Patent Examiner, Art Unit 1791